

REMARKS

The Examiner's Office Action mailed July 16, 2009, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of July 16, 2009, and submit that the above Amendments and the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 1-7 are now in form for allowance.

Status of Claims

Claims 1 and 3-7 are pending in the application. Claims 1, 4 and 5 have been withdrawn from consideration. Claim 1 has been amended for clarification. No new matter has been added.

Rejection of Claims 3, 6, and 7 under 35 USC 102(b)

Reconsideration is requested of the rejection of claims 3, 6, and 7 under §102(b) as being anticipated by Fraatz (Abstract only: Abstracts of the interscience conference on antimicrobial agents and chemotherapy, 2002, volume 42, pp. 189).

The claimed invention is directed to a method for the systemic treatment of bacterial infections of the oral cavity that includes administering to a human or animal in need thereof an effective amount of an antibiotic. Claim 3 requires the antibiotic to be an 8-cyanoquinolone, specifically pradofloxacin.

The Examiner states that although Fraatz does not disclose administering pradofloxacin for the purpose of systemic treatment of bacterial infections of the oral cavity, Fraatz does disclose the oral administration of pradofloxacin for the treatment of bacterial infections in dogs and cats. The Examiner then concludes that since these are the same methods Fraatz inherently anticipates the claim. Applicants respectfully disagree.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *In re Schreiber*, 128 F.3d

1472, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). First, Applicants suggest that the claim has not been properly construed by the Examiner. Only when a claim is properly understood can a determination be made whether the claim "reads on" an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351, 57 USPQ2d 1747, 1751-52 (Fed. Cir. 2001). In this case, claim 1 and therefore claim 3 require "systemic treatment of bacterial infections of the oral cavity" in a "human or an animal in need of such treatment." The issue reduces to whether such a human or animal must know that he/it is in need of the treatment of that condition.

A similar issue arose in the *Raporot v. Dement* case, 254 F.3d 1053 (Fed. Circ. 2001) and in the *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Circ. 2003). In *Raporot*, the appeal court interpreted the preamble phrase "for treatment of sleep apneas" to require that the method be practiced with the intent to achieve the objective stated in the preamble. The court in *Jansen* stated "[t]he preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather it is a statement of the intentional purpose for which the method must be performed." As such, the claim should be read to include the "systemic treatment of bacterial infections of the oral cavity" in a "human or an animal in need of such treatment."

Second, Applicants suggest that if properly construed, the claim is not anticipated by Fraatz. There is no disclosure in Fraatz of the use of pradofloxacin for the systemic treatment of bacterial infections of the oral cavity. The Fraatz publication focuses on the serum pharmacokinetics of pradofloxacin in dogs after administration of pradofloxacin, not systemic treatment of bacterial infection of the oral cavity. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746, 1749 (Fed. Circ. 1991). Fraatz has not attempted to demonstrate systemic treatment of bacterial infections of the oral cavity. Instead, Fraatz merely discusses pharmacokinetics.

As such Applicants submit that Fraatz does not anticipate claims 3, 6, and 7 and the current invention is novel and non-obvious in view of Fraatz.

Rejection of Claims 3, 6, and 7 under 35 USC 103(a)

Reconsideration is requested of the rejection of claims 3, 6, and 7 under §103(a) as being unpatentable over Schultz et al (US 2003/0045544) in view of Vetter et al. (US 5808076) and Himmler et al (Abstracts of the interscience conference on Antimicrobial Agents and Chemotherapy (2002)).

Schultz et al. teach the use of chemotherapeutic agents, such as described by formula (I), for topical and local treatment of diseases caused by bacteria in humans and animals. Schultz focuses the administration of the agents is topically or locally (see paragraphs 37-77). As the Examiner correctly stated, Schultz does not disclose the systemic treatment of bacterial infections or the oral cavity diseases as recited by claim 7.

Vetter et al. teach quinolone embonates, specific formulations of quinolones that are administered orally. Vetter et al., however, does not teach CN quinolones, such as pradofloxacin. In addition, Vetter et al. does not disclose the systemic treatment of bacterial infections of the oral cavity, unlike as suggested by the Examiner.

Himmler et al. teach the synthesis and in vitro activity of pradofloxacin. The in vitro activity shown is with regards to *E. Coli*, *S. aureus* and *S. intermedius*.

The Examiner states that it would have been prima facie obvious for one skilled in the art at the time of the invention to use pradofloxacin to systemically treat bacterial infections of the oral cavity in humans or animals in need thereof. The Examiner comes to this conclusion by stating that Schultz et al. teach fluoroquinolones for the local or topical treatment of oral cavity infections, Vetter et al. teach systemic activity of fluoroquinolones against various bacteria, and therefore someone skilled in the art would combine the teachings of Shultz et al. and Vetter et al. to develop a method treating bacterial infections of the oral cavity by systemic administration of pradofloxacin and other fluoroquinolones.

Applicants respectfully disagree, as noted above Vetter et al. do not teach systemic treatment of bacterial infections of the oral cavity. Vetter et al. do not teach systemic treatment at all.

In addition, the Examiner uses Himmeler et al. to show that one skilled in the art would utilize pradofloxacin as it showed the lowest MIC in comparison to other fluoroquinolones in inhibiting *E. Coli*, *S. aureus* and *S. intermedius*. However, none of these are infections of the oral cavity. As such, Himmeler would not be used by someone skilled in the art trying to develop a method of systemically treating a bacterial infection of the oral cavity.

As such Applicants submit claims 3, 6, and 7 are patentable over Schultz et al. in view of Vetter et al. and Himmeler et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are novel and not obvious over the cited references and request withdrawal of all rejections and allowance of the claims.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889